SEP 17 2003

K032611

Summary of Safety and Effectiveness
Lyphochek® Coagulation Control Level 4

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

Maria Zeballos
Regulatory Affairs Specialist
Telephone: (949) 598-1367

Date of Summary Preparation

August 11, 2003

2.0 Device Identification

Product Trade Name:	Lyphochek® Coagulation Control Level 4
Common Name:	Plasma Coagulation Control
Classifications:	Class II
Product Code:	GGN
Regulation Number:	21 CFR 864.5425

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek® Coagulation Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K012722

4.0 Description of Device

Lyphochek® Coagulation Control is prepared from human plasma, with added purified biochemicals (tissue extract from animal origin), and preservatives. The control is provided in lyophilized form for increased stability.

5.0 Statement of Intended Use

Lyphochek® Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems

6.0 Comparison of the new device with the Predicate Device

The new Lyphochek® Coagulation Control Level 4 claims substantial equivalence to the Lyphochek® Coagulation Control currently in commercial distribution (K012722). The new Lyphochek® Coagulation Control is a tri-level (Level 1, 2 and 3) product and the current product is a single level (Level 4) product.

Characteristics	Bio-Rad Lyphochek® Coagulation Control (Predicate Device K012722)	Bio-Rad Lyphochek® Coagulation Control (New Device)
	Similarities	
Intended Use	Lyphochek® Coagulation Control is intended for use as a quality control plasma control to monitor the precision of citrated coagulation systems.	Lyphochek® Coagulation Control is intended for use as a quality control plasma control to monitor the precision of citrated coagulation systems.
Form	Lyophilized	Lyophilized
Matrix	Human plasma	Human plasma
Open Vial stability	24 hours at 2 to 25°C	24 hours at 2 to 25°C
Storage (Unopened)	2 to 8°C Until expiration date	2 to 8°C Until expiration date
Analytes	• Prothrombin Time (PT) • Activated Partial Thromboplastin Time (APTT) • Fibrinogen • Antithrombin II (AT III) • Thrombin Time (TT)	• Prothrombin Time (PT) • Activated Partial Thromboplastin Time (APTT) • Fibrinogen • Antithrombin II (AT III) • Thrombin Time (TT)
Fill size	1 mL	1 mL
	Differences	
Formulation	Does not contain constituents of animal origin	Contain constituents of animal origin
Levels	Levels 1, 2 and 3 (Does not include level 4)	Level 4 (Does not include levels 1, 2 or 3)

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Lyphochek® Coagulation Control Level 4. Product claims are as follows:

7.1 Open vial: Once the control material is reconstituted, all analytes will be stable for 24 hours when stored tightly capped at 2-25°C

7.2 Shelf Life: Three years when stored at 2-8 °C

7.3 Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 2003

Ms. Maria Zeballos
Regulatory Affairs Specialist
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, California 92618-2017

Re: k032611
Trade/Device Name: Lyphochek® Coagulation Control Level 4
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Studies
Regulatory Class: II
Product Code: GGN
Dated: August 11, 2003
Received: August 25, 2003

Dear Ms. Zeballos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510 (k) Number (if known): K032611

Device Name: **Lyphochek® Coagulation Control Level 4**

Indications for Use:

Lyphochek® Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems.

Methods:

- Diagnostica Stago Neoplastine C1 Plus (PT)
- Diagnostica Stago PTT Automate
- Diagnostica Stago Fibrinogen
- Diagnostica Stago Stachrom (AT III)
- Diagnostica Stago Thrombin
- Axis Shield Nycotest
- Axis Shield Cephotest

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032611

(PLEASE DO NOT WRITE BELOW THE LINE-CONINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____